Goldsboro Milling Company
P. O. Drawer 10009
Goldsboro, NC 27532
(919) 778-3130
September 3, 1998

FDA Dockets Branch (HFA-305)
Food and Drug Administration
5603 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0339, in support of the public hearing on CVM required by Section 406(b) of the FDA Modernization Act.

To Whom It May Concern:

The company for which I administer health services produces over 250 million pounds of turkey and over 250 million pounds of pork per year. Our laboratory oversees all diagnostic efforts in support of these animals and the breeding stock associated with them, and oversees and/or prescribes any indicated medications as appropriate. Our vertically integrated operation employs 3 veterinarians, a veterinarian/PhD, and 3 PhD's in poultry and food science.

I believe CVM can significantly enhance review of submissions, more effectively utilize personnel, protect the public health, and give the end-users of CVM-reviewed products the protection they want by significantly reducing the rigor of efficacy requirements for pharmaceuticals for the poultry and swine industries. Certainly, all current efforts to protect human health and the environment must remain in place, but just as certainly, the poultry industry in particular, and the swine industry to an increasing degree, are much better equipped to design, evaluate, and review the efficacy of products used to produce animal protein than either the sponsors or the Center.

The scientific staff of modern swine and poultry production companies can quickly identify "snake-oil" products, and is much better suited to examine potential interactions with individual production systems than either CVM or sponsor staffs. The real efficacy experts are employed by the end users - the production companies; modern economic pressures demand it. The Center should be only minimally concerned with efficacy testing for products for these industries since the true testing will occur in-house at the production companies under a degree of rigor that cannot be equalled in the laboratory.

If necessary, I would propose that all submissions involving chickens, turkeys, and swine require presubmission conferences, and that an active end-user representative, chosen from the Association of Veterinarians in Broiler Production, the Association of Veterinarian in Turkey Production, or the American Association of Swine Practitioners as appropriate, be included in the efficacy portions of that conference. Such individuals could certainly execute any confidentiality agreements necessary to perform this voluntary service. This device would provide both the Center and the sponsor much better guidance on the degree of protection from non-efficacious products the end-users desire than has ever existed. Frankly, I have been appalled by some of the efficacy trials proposed by sponsors, and some requirements that were represented to me to be imposed by the Center. Both seem out-of-touch, and certainly have not guaranteed efficacy under field conditions. Likewise, by extra-label use, some products are certainly efficacious for conditions for which they have no claims. Clearly, this argues against efficacy testing as it currently exists.

98N-339V

EC2

This simple measure should release time and money for both the sponsors and the Center to more actively pursue areas where there are critical needs: Pharmaceuticals to relieve the pain and suffering related to PEMS, histomoniasis, trichomoniasis, coccidiosis, broodiness, bordetellosis, ORT, and cellulitis (this list is not inclusive; these are merely the most glaring).

I also fail to see why a Veterinary Feed Directive should not permit the use of combinations of any product individually approved in the feed. The current approval system is a marked improvement over the previous system, but is still needlessly cumbersome, slow, and expensive compared to allowing experienced, licensed, accredited graduate veterinarians with advanced degrees to employ their skills to improve animal well-being.

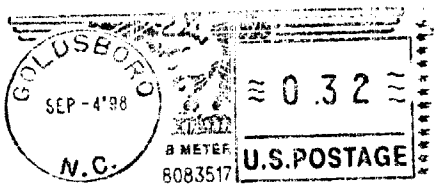
I completely concur with Joel Brandenberger's comments from the National Turkey Federation; my comments are submitted in support, and to inform the Center and sponsors of the nature and needs of modern poultry and swine production.

Respectfully,

Eric Gonder, DVM, MS, PhD, PAS, ACPV

Gonder

P. O. Box 10009 Goldsboro, NC 27532



FDA Dockets Branch (HFA-305)
Food and Drug Administration
5603 Fishers Lane, Room 1061
Rockville, MD
20852